

**PHARMACY EXAMINING BOARD
MADISON, WI
MINUTES
NOVEMBER 11, 2003**

PRESENT: Cynthia Benning, R.Ph.; Michael Bettiga, R.Ph.; John Bohlman, R.Ph.; Georgina Forbes, Dan Luce, R.Ph.; Charlotte Rasmussen; Susan Sutter, R.Ph.

STAFF PRESENT: Tom Ryan, Bureau Director; William Black, Legal Counsel; Pamela Meicher, Program Assistant; DOE Staff

GUESTS: Lindsey Sutter; Greg Primuth, Walgreen Co.; Elizabeth Nelson, Women's International Pharmacy; Jamie Stat Paynter, Dean Pharmacy; Tom Engels, Pharmacy Society of Wisconsin; Larry P. Edwards, Department of Corrections; Ann Mertz, DPH-4, UW School of Pharmacy; Hannel Tibagwa, UW Hospital Pharmacy; Carrie Boeckelman, UW Health Pharmacy; Alisa Kroon, UW School of Pharmacy; Tarita Roberts, UW Hospital Pharmacy

CALL TO ORDER

Chair Susan Sutter called the meeting to order at 9:01 a.m. A quorum of 7 members was present.

AGENDA

Amendments to agenda:

Proposed Stipulation 03 PHM 028
Puritan Medical Products Inc., approval for licensure
Administrative Warning 02 PHM 031
Letter from Aida Hot covering her internship
Scope Statement relating to uniform reexamination restrictions and other penalties for applicants who cheat on examinations.
Clearinghouse Report to Agency Rule 03-096
Preliminary draft relating to the administration of vaccines by persons supervised by a pharmacist
NABP's actions addressing the practice of importation of prescription medications
Letter to the Honorable Peggy Lautenschlager covering illegal Canadian importation of prescription drugs.
Letter to Secretary Donsia Strong Hill covering illegal Canadian importation of prescription drugs

MOTION: Michael Bettiga moved, seconded by Dan Luce, to approve the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF OCTOBER 15, 2003

Corrections to minutes:

Page 3 – Correct first motion to read: In favor of legislation in LRB 2565/2 short of the label requirement.

Page 3 – Correct Drug Labeling Bill to AB 560

Page 4 – Correct second motion to read: In favor of a requirement that FDA approved drugs from Canada come through United States pharmacies, not drug brokers.

Page 5 – Correct the second sentence under NABP Legislative Conference Update to read: Mr. Luce will provide the Board with the USP criteria used when making their decision of not allowing repackaging of bubble packs.

MOTION: Cynthia Benning moved, seconded by Dan Luce, to approve the corrections to the minutes of October 15, 2003. Motion carried unanimously.

ADMINISTRATIVE REPORT

Deputy Secretary Mary Schlaefter discussed the state of the Department. Ms. Schlaefter advised the Board that the department has to reduce meetings and is working on an operating budget. This will result in a reduction in the number of Pharmacy Board meetings the Department can commit to staff from 12 in 2003 to 7 in 2004. The revised 2004 meeting schedule will indicate which listed meeting dates are cancelled. The department is also looking at all statutory requirements and workload issues, such as enforcement cases. DOE processes are being reviewed to ensure they are standard and consistent when addressing cases and monitoring.

The Board expressed concerns about the reduction in meetings. It requested a comparison of the frequency of other state's Board meetings. After a detailed discussion, Deputy Secretary Schlaefter said that she would request that Elizabeth Reinwald address the Board at its December meeting to describe budget dilemmas. She also advised the Board that a request has been made to the Legislative Audit Bureau to complete the fee study ordered by the Legislative Audit Committee earlier than June 2004.

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, in favor of having the 2004 meeting date schedule changed to reflect months that the Board may decide a meeting is necessary due to needs of the business. Motion carried unanimously.

Chair Susan Sutter asked the Board if she could speak at the Milwaukee Symposium January 25 to discuss stressors in pharmacy.

MOTION: Michael Bettiga moved, seconded by Charlotte Rasmussen, in favor of Chair Susan Sutter speaking at the January 25, 2004 Symposium to discuss stressors in pharmacy. Motion carried unanimously.

PRESENTATION OF PROPOSED STIPULATION AND FINAL DECISION AND ORDER IN CASE NUMBER 03 PHM 028 BY ATTORNEY MICHAEL BERNDT

DOE Attorney Michael Berndt presented the Proposed Stipulation, Final Decision, and Order in case number 03 PHM 028. This matter will be deliberated on in closed session.

SUMMARY REPORTS ON PENDING COURT CASES, DISCIPLINARY CASES, ADMINISTRATIVE RULES AND LEGISLATION

AB 560

The Board briefly discussed Assembly Bill 560 and the draft letter from Chair Susan Sutter to State Representative Leah Vukmir.

LRB 2565/2

The Board briefly discussed the letter sent to Senator Wieckert relating to the label requirement.

MOTION: Cynthia Benning moved, seconded by Michael Bettiga, in favor of amending the letter to specifically oppose the labeling requirement. Motion carried unanimously.

The Board noted that the central fill legislation will go into effect on 12/01/03.

WIS. ADMIN. CODE § PHAR 7.05 – RECORDS MAINTENANCE – REVIEW AND REVISION

William Black presented the revised rule to the Board. The Board will re-review the revision at a future meeting.

WIS. ADMIN. CODE § PHAR 6.08 – ALARM SECURITY – REVIEW AND APPROVE FOR SUBMISSION TO THE CLEARINGHOUSE

William Black presented the proposed modification of the rule to the Board for approval.

MOTION: Michael Bettiga moved, seconded by Cynthia Benning, in favor of approving and sending Wis. Admin. Code § Phar 6.08 to the Clearinghouse. Motion carried unanimously.

WIS. ADMIN. CODE § PHAR 7.04 – CBRF RETURNS – REVIEW OF DRAFT SCOPE STATEMENT AND AUTHORIZE FOR PUBLICATION

MOTION: Cynthia Benning moved, seconded by Charlotte Rasmussen, in favor of authorization to publish the Scope Statement for Wis. Admin. Code § Phar 7.04. Motion carried unanimously.

PUBLIC HEARING – WIS. ADMIN. CODE § PHAR 6.04 – MODIFICATION OF PROFESSIONAL SERVICE REQUIREMENTS DURING PHARMACIST ABSENCE

A public hearing was held on Wis. Admin. Code § Phar 6.04, relating to the modification of professional service requirements during pharmacist absence. There were no public comments presented at the hearing. The Board will re-review the Clearinghouse comments at the December meeting.

COMPLIANCE QUESTION – STACY RICARD LAWLER, RPH – NEENAH, WI

The Board re-addressed the compliance question relating to patient consultations on prescription refills. After a brief discussion the Board indicated that they would be open to considering a variance request for a new business model, but will not make a rule change relaxing patient consultations on refills.

MOTION: Michael Bettiga moved, seconded by John Bohlman, in favor of being receptive to considering a variance for a business model similar to Ms. Lawler's, relating to consultations on prescription refills. Motion carried unanimously.

REVIEW AND CONSIDERATION OF APPLICATION FOR APPROVAL (FLOOR PLAN AND ALARM SYSTEM) – ACCUPAX, INC. – FITCHBURG, WI

The Board briefly discussed the application from Accupax, Inc. Legal Counsel William Black will draft a letter requesting more information from Accupax, Inc., including their business plan covering dispensing directly to patients.

VARIANCE REQUEST – HANNET TIBAGWA, PHARMD, MS, UNIVERSITY OF WISCONSIN HOSPITALS AND CLINICS – MADISON, WI

No variance was granted at this time. The application will be considered at a future meeting after the variance request is further delineated.

CANADIAN REIMPORTATION

Chair Susan Sutter gave an overview of reimportation of drugs from Canada. The Board reviewed articles relating to storefronts in Wisconsin, NABP actions, and the Oklahoma Findings of Facts and Conclusions of Law. The Board would like to take immediate action against reimport pharmacies.

Chair Sutter has sent letters and delivered packets addressing reimportation to legislators. Ms. Sutter has requested that the Attorney General respond to the Board on this issue. Ms. Sutter plans to meet with the DRL Secretary, the FDA, DHFS and legislative staff to discuss this further.

Ms. Sutter reviewed the letter she sent to DOE Division Administrator Sandra Rowe addressing possible Wisconsin law violations. The Board has requested that Michael Berndt share their position with Ms. Rowe and advise Chair Sutter of any further information.

MOTION: Charlotte Rasmussen moved, seconded by Dan Luce, in favor of pursuing every avenue to parallel with Oklahoma, demanding the closing of all Canadian drug reimportation locations. Motion carried unanimously.

MOTION: Charlotte Rasmussen moved, seconded by John Bohlman, in favor of delegating Chair Susan Sutter as the Board spokesperson addressing Canadian reimportation. Motion carried unanimously.

REVIEW OF REQUEST FOR LEGISLATION, WIS. STAT. § 450.035

William Black discussed the draft language that would allow pharmacists to delegate to interns administration of certain products, devices, or vaccines, as long as the intern has successfully completed a course of study and training. Mr. Black will provide a draft of the proposed revision at a future meeting.

2004 MPJE TIME AND TASK SCHEDULE FOR PARTICIPATING BOARDS

MOTION: Michael Bettiga moved, seconded by Dan Luce, in favor of delegating John Bohlman and William Black to attend the 2004 MPJE state-specific Review Meeting #1, January 23-25, 2004, in Phoenix/Scottsdale, Arizona. Motion carried unanimously.

USP RE-PROCESSING – UPDATE

Cynthia Benning joined the USP Packaging, Storage and Distribution Committee by teleconference on November 6. The USP discussed expired unit dose drugs, stability issues and the splitting of lot numbers. The USP did not offer any data to support their stability conclusions. Ms. Benning discussed the unnecessary waste this causes for both consumers and public agencies. She asked if their decision to disallow repackaging is enforceable. USP indicated that they believe it is. William Black will work with Ms. Benning on an issues outline from this call for the December Board meeting.

INFORMATIONAL ITEMS

Dan Luce indicated the main topics discussed at a recent NABP meeting he attended were technician education, competency assessment and illicit drugs.

CLOSED SESSION

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen to convene to closed session to deliberate on case(s) following hearing (Wis. Stat. § 19.85 (1) (a)); consider closing disciplinary investigation(s) with administrative warning (Wis. Stat. § 19.85 (1) (b), and Wis. Stat. § 440.205); consider individual histories or disciplinary data (Wis. Stat § 19.85 (f)); and to confer with legal counsel (Wis. Stat § 19.85 (1) (g)). Motion carried by roll call vote: Cynthia Benning-yes, Michael Bettiga-yes, John Bohlman-yes, Georgina Forbes-yes, Dan Luce-yes, Charlotte Rasmussen-yes, Susan Sutter-yes.

Open session recessed at 1:10 p.m.

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

MOTION: Charlotte Rasmussen moved, seconded by Michael Bettiga, to reconvene into Open Session at 2:35 p.m. Motion carried unanimously.

VOTING ON ITEMS DELIBERATED OR CONSIDERED IN CLOSED SESSION

REVIEW OF SCORING CANDIDATE #1016 FROM OCTOBER 14, 2003 EXAMINATION – DARWIN TICHENOR

MOTION: Dan Luce moved, seconded by Michael Bettiga, in favor of accepting the original score of candidate #1016 from the 10/14/03 examination. Motion carried unanimously.

DELIBERATION OF ADMINISTRATIVE WARNING IN CASE NUMBER 03 PHM 047

The Board has requested that DOE use Arthur Thexton's worksheet as a guide to ensure that Orders are worked consistently. The Board believes that failure to consult should be a reprimand. The Board has sent this case back to DOE for reconsideration of a Reprimand instead of an Administrative Warning for the pharmacist.

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to close case 03 PHM 047 against the pharmacy, as a no violation. Motion carried unanimously.

APPLICATION REVIEW – LAURA MIGHTON ERYOU

The Board decided after reviewing the application of Laura Mighton Eryou that she must take the FPGEC.

ROGER IVERSON – REQUEST FOR 3 MONTH STAY

MOTION: Michael Bettiga moved, seconded by Dan Luce, to grant a 3 month stay of suspension in the matter of Roger Iverson. Motion carried unanimously.

JANET KRUEGER - REQUEST FOR 3 MONTH STAY

MOTION: Cynthia Benning moved, seconded by John Bohlman, to grant a 3 month stay of suspension in the matter of Janet Krueger. Motion carried unanimously.

DONALD LEETZ – REQUEST FOR 3 MONTH STAY WITH MODIFICATIONS

MOTION: Cynthia Benning moved, seconded by Michael Bettiga, to grant a 3 month stay of suspension in the matter of Donald Leetz and deny the request for 8 hours of pharmacist in charge until his employer supports it. Motion carried unanimously.

LANCE LUNDSTAD – REQUEST FOR 3 MONTH STAY WITH MODIFICATIONS

MOTION: Michael Bettiga moved, seconded by Charlotte Rasmussen, to grant a 3 month stay of suspension in the matter of Lance Lundstad and approve the order modification of 8 hours of pharmacist in charge. Motion carried.

LUIGI MICELI – REQUEST FOR 3 MONTH STAY WITH MODIFICATIONS

MOTION: Michael Bettiga moved, seconded by Charlotte Rasmussen, to grant a 3 month stay of suspension in the matter of Luigi Miceli and approve the order modification of 8 hours of pharmacist in charge. Motion carried.

THOMAS PIRE – REQUEST FOR 3 MONTH STAY

MOTION: Cynthia Benning moved, seconded by Georgina Forbes, to grant a 3 month stay of suspension in the matter of Thomas Pire. Motion carried unanimously.

JOHN SCHMITT – REQUEST FOR 3 MONTH STAY WITH MODIFICATIONS

MOTION: Cynthia Benning moved, seconded by Charlotte Rasmussen, to deny a 3 month stay of suspension in the matter of John Schmitt because he did not provide supervisor work reports. Michael Bettiga abstained. Motion carried.

GREGORY TECHE – REQUEST FOR 3 MONTH STAY

MOTION: Michael Bettiga moved, seconded by Dan Luce, to grant a 3 month stay of suspension in the matter of Gregory Teche. Motion carried unanimously.

DELIBERATION OF PROPOSED STIPULATION 03 PHM 028

MOTION: Cynthia Benning moved, seconded by Michael Bettiga, to adopt the Final Decision, Order and Stipulation in the matter of case 03 PHM 028. Motion carried unanimously.

ADMINISTRATIVE WARNING 02 PHM 031

MOTION: Michael Bettiga moved, seconded by Dan Luce, to close case 02 PHM 031 with an Administrative Warning. Motion carried unanimously.

APPROVAL FOR LICENSURE – PURITAN MEDICAL PRODUCTS, INC.

MOTION: John Bohlman moved, seconded by Michael Bettiga, to grant a license to Puritan Medical Products, Inc. Motion carried unanimously.

ADJOURNMENT

MOTION: Michael Bettiga moved, seconded by Georgina Forbes, to adjourn the meeting at 3:32 p.m. Motion carried unanimously.

Next Meeting Wednesday, December 10, 2003